Medical Coverage Policy | Autologous Platelet-Derived Growth Factors (i.e. Platelet-Rich Plasma)

EFFECTIVE DATE: 11|15|2016
POLICY LAST UPDATED:02|03|2021

OVERVIEW
This policy documents the coverage determination for autologous platelet-derived growth factors (PDGF) (i.e., platelet-rich plasma [PRP]). Autologous platelet-derived growth factors have been investigated as wound-healing products.

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MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Coverage of autologous platelet-rich plasma (PRP) for Medicare Advantage Plans members is allowed only as part of a Centers for Medicare and Medicaid (CMS) approved clinical trial. Refer to Related Policy section.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plan policies. Therefore, Medicare Advantage Plan policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products
Autologous blood-derived preparations (i.e., platelet-rich plasma) are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary among groups. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
A variety of growth factors have been found to play a role in wound healing, including platelet-derived growth factor (PDGF), epidermal growth factor, fibroblast growth factors, transforming growth factors, and insulin-like growth factors. Autologous platelets are a rich source of PDGF, transforming growth factors (that function as a mitogen for fibroblasts, smooth muscle cells, and osteoblasts), and vascular endothelial growth factors.

Autologous platelet concentrate suspended in plasma, also known as platelet-rich plasma (PRP), can be prepared from samples of centrifuged autologous blood. Exposure to a solution of thrombin and calcium chloride degranulates platelets, releasing various growth factors, and results in the polymerization of fibrin from fibrinogen, creating a platelet gel. The platelet gel can then be applied to wounds or may be used as an adjunct to surgery to promote hemostasis and accelerate healing. In the operating room setting, PRP has been investigated as an adjunct to a variety of periodontal, reconstructive, and orthopedic procedures. For example, bone morphogenetic proteins are a type of transforming growth factor, and thus PRP has been used

in conjunction with bone-replacement grafting (using either autologous grafts or bovine-derived xenograft) in periodontal and maxillofacial surgeries.

PRP is distinguished from fibrin glues or sealants, which have been used for many years as a surgical adjunct to promote local hemostasis at incision sites. Fibrin glue is created from platelet-poor plasma and consists primarily of fibrinogen. Commercial fibrin glues are created from pooled homologous human donors; Tisseel® (Baxter International) and Hemaseel® (Haemacure Corp.) are examples of commercially available fibrin sealants. Autologous fibrin sealants can also be created from platelet-poor plasma.

For individuals who have chronic wounds or acute surgical or traumatic wounds who receive PRP, the evidence includes meta-analyses of a number of small controlled trials. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity. In individuals with lower extremity diabetic ulcers, PRP demonstrated an improvement over the control groups in complete wound closure and healing time, but moderate to high risk of bias and imprecision preclude drawing conclusions on other important outcomes such as recurrence, infection, amputation, and quality of life. In individuals with venous ulcers, PRP did not demonstrate an improvement over the control groups in complete wound closure, recurrence, wound infection or quality of life, although imprecision likely precluded identifying differences on these outcomes. In individuals with pressure ulcers, although PRP reduced wound size, other important outcomes such as complete wound closure were not measured. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The Centers for Medicare & Medicaid Services (2012) revised its national coverage decision on autologous blood-derived products for chronic non-healing wounds. This revision replaces prior noncoverage decisions.

The Centers for Medicare & Medicaid Services covers autologous PRP only for patients who have chronic non-healing diabetic, pressure, and/or venous wounds and when all of the following conditions are met:

"The patient is enrolled in a clinical research study that addresses the following questions using validated and reliable methods of evaluation.

"The clinical research study must meet the requirements specified below to assess the effect of PRP for the treatment of chronic non-healing diabetic, venous and/or pressure wounds. The clinical study must address:

"Prospectively, do Medicare beneficiaries that have chronic non-healing diabetic, venous and/or pressure wounds who receive well-defined optimal usual care, along with PRP therapy, experience clinically significant health outcomes compared to patients who receive well-defined optimal usual care for chronic non-healing diabetic, venous and/or pressure wounds as indicated by addressing at least one of the following:

a. Complete wound healing?
b. Ability to return to previous function and resumption of normal activities?
c. Reduction of wound size or healing trajectory which results in the patient's ability to return to previous function and resumption of normal activities?"

CODING

The following code is allowed for Medicare Advantage Plans as part of a CMS approved clinical study and not medically necessary for Commercial products:

G0460 Autologous platelet rich plasma for non-diabetic chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment (Revised text 1/1/2022)

Claims for services rendered as part of a CMS approved clinical study must be billed with an appropriate modifier:

Modifier Q0 – Investigational clinical service provided in a clinical research study that is in an approved research study (Medicare Advantage Plans claims filed without the Q0 modifier will deny as not covered)
Note: If you are treating a Medicare Advantage Plan member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy Clinical Trials for Medicare Advantage Plans.

RELATED POLICIES

Clinical Trials Medicare Advantage Plans
Medicare Advantage Plans National and Local Coverage Determinations
New Technology and Miscellaneous Services

PUBLISHED

Provider Update, April 2021
Provider Update, May 2020
Provider Update, May 2019
Provider Update, January 2019
Provider Update, December 2017
Provider Update, January 2017
Provider Update, Apr 2015
Provider Update, Sep 2014

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